

REMARKS

Status of Claims

Claims 1-7 and 21-41 are pending. Claim 1 is amended in order to make some grammatical changes. In addition, the phrase "one or more particulate drugs" has been changed to "a particulate drug" in order to claim a particular embodiment of the invention. New claims 21-41 have been added. These claims are supported by the specification at page 8, lines 20-22. Claims 8-10 are canceled in this Amendment, and 11-20 were previously canceled.

Amendment to the Specification

The specification has been amended to correct a typographical error. No new matter has been added.

Information Disclosure Statement

In the Office Action, the Examiner indicates that on December 7, 2005, applicant submitted several non-patent references. These references, as well as various other references, were listed in the Information Disclosure Statement filed on November 21, 2005. The Examiner states that "Examiner has considered the references submitted by applicant." Applicants appreciate the Examiner's consideration of the references. However, applicant's representative cannot locate an initialed copy of the PTO/SB/08 form attached to the IDS filed on November 21, 2005. Applicant hereby requests the Examiner to initial the PTO/SB/08 attached to the IDS filed on November 21, 2005 and to return an initialed copy to the undersigned. A copy of the Information Disclosure Statement filed on November 21, 2005 (without any references) is attached

for the Examiner's convenience. If the Examiner needs an additional copy of any of the references, he is requested to contact the undersigned.

Double Patenting Rejection

Claims 1-10 are rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-5, 12 and 13 of U.S. Patent 6,743,413, in view of Greenleaf U.S. 5,427,282. In making the rejection, the Examiner states:

"...while the instant claims are drawn to a method of preparing a metered dose inhaler, patented claims are drawn to a metered dose inhaler. The contents of the metered dose inhaler of patented claims are identical to that of the formulation to be added to the metered dose inhaler of instant claims. Patented claims do not recite a metered dose inhaler having a metering valve that has a valve seal comprising surfactant. ..."

This rejection is respectfully traversed. Reconsideration and withdrawal thereof are respectfully requested.

Claims 1-4 in the present application are directed to:

1. A process for preparing a metered dose inhaler comprising a container closed with a metering valve, said metered dose inhaler containing a pharmaceutical composition suitable for inhalation by a patient, comprising the steps of:

preparing a pharmaceutical suspension formulation consisting essentially of a therapeutically effective amount of a particulate drug sufficient to provide a plurality of therapeutically effective doses of drug and a propellant selected from the group consisting of HFC 134a, HFC 227, and a mixture thereof, wherein said pharmaceutical suspension formulation contains no surfactant or less than an effective stabilizing amount of surfactant; and

providing said drug and said propellant in said metered dose inhaler to prepare a metered dose inhaler containing said pharmaceutical composition.

2. The process of claim 1, wherein said metering valve contains a surfactant as a lubricant for the metering valve.

3. The process of claim 2, wherein said metering valve comprises a valve stem and said valve stem contains a surfactant as a lubricant for the valve stem.

4. The process of claim 2, wherein a pharmaceutical suspension is first prepared in bulk outside of said metered dose inhaler and then transferred to said metered dose inhaler equipped with said metering valve using a valve to valve transfer method.

Therefore, the presently pending claims specifically provide for a method of making a metered dose inhaler. Claim 2 specifically provides for the presence of a surfactant as a lubricant for the metering valve. Small amounts of lubricant can be picked up by the pharmaceutical suspension during filling of the metered dose inhaler, especially when a valve to valve transfer method is used. This concept is neither taught nor suggested by the claims in U.S. Patent 6,743,413. The '282 patent has a filing date which is more than 2 years after the May 4, 1992, filing date of applicants grandparent application, to which the claims of the present application are fully supported. Therefore, the '282 patent cannot be used as a "prior art" reference, either alone or in combination with the claims of the '413 patent.

Claims 1-10 are rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent 5,427,282, in view of Schultz et al. U.S. 6,743,413. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are respectfully requested.

The claims of the '282 patent are directed to an aerosol valve. The claims of the '282 patent make no mention of a pharmaceutical suspension formulation that consists essentially of the components claimed in claim 1 of the present application. This is an essential feature of the present claims. This deficiency in the claims of the '282 patent is not cured by the '413 patent because the '413 patent is not prior art and therefore cannot be properly combined with the

claims of the '282 patent. It is noted that the '413 patent issued from the application which is the parent application of the present application.

Conclusion

A full and complete response has been made to all issues as cited in the Office Action. Thus, Applicants respectfully request that a timely Notice of Allowance issue for the present case. As stated above, it is submitted that the present application is in condition for allowance and that the obviousness-type double patenting rejections are improper. However, if necessary for allowance, applicants will file a Terminal Disclaimer over the '413 patent, which issued from the parent application of the present application. In terms of patent term, any patent that will issue from the present application will already have a shorter, unextended patent term than the two cited patents; therefore, there is no extension of patent term by granting the present application.

If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to contact Gerald M. Murphy, Jr. (Reg. No. 28,977) at the offices of Birch, Stewart, Kolasch & Birch, LLP.

Application No. 10/820,817

Docket No.: 2801-0187P

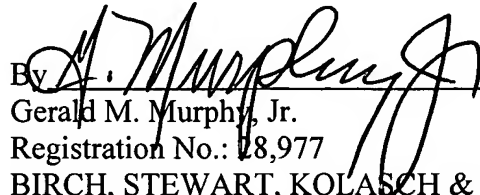
Art Unit 1615

Reply to Office Action of February 17, 2006

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Dated: June 16, 2006

Respectfully submitted,


By _____
Gerald M. Murphy, Jr.
Registration No.: 18,977
BIRCH, STEWART, KOLASCH & BIRCH, LLP
8110 Gatehouse Road, Suite 100 East
P.O. Box 747
Falls Church, Virginia 22040-0747
(703) 205-8000
Attorney for Applicant

Enclosures:

Copy of IDS filed November 21, 2005